K092421

510(k) Summary

FEB 12 2010

Responsible Persons:

Bernd Maier, Director of OEM Business (responsible for Design evaluation)
Reinhold Blazejewski, Fa.MediTech, (responisible for production)
Klaus Moser, Head of Service (responsible for Technical Requests)
Ulrich Henzler/Gabriela Trompler, QAM (Responsible for Regulations and Documentation

Date Summary prepared: June 22, 2009

Device Name: AlphaScope Hysteroscope, fiber optic

Device Description (807.92):
AlphaScope Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures. AlphaScope Hysteroscope is used with Hysteroscope Sheaths to provide access to the uterine cavity during diagnostic and operative hysteroscopic procedures.

The use of AlphaScope Hysteroscope is restricted for the use of endoscopic surgeons and qualified assistants.

AlphaScope Hysteroscopes are re-useable, they can be sterilized by 134 C Degrees Steam Autoclave

Classification accord. MDD 93/42 in Risk Class IIa
Accord. CFR in Risk Class II

Common Name: **Hysteroscopes** and accessories

Classification names	Product code	CFR Regulation #
Hysteroscope, fiberoptic	**85 HIH**	**884.1690**

Indications for Use (807.92)
AlphaScope Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

AlphaScope Hysteroscope is used with Hysteroscope Sheaths to provide access to the uterine cavity during diagnostic and operative hysteroscopic procedures.

Industry Standards/Performance Data (808.92)
We certify the conformity with all European Norms and directives. AlphaScope Hysteroscopes and their accessories are CE-marked.
Also they are in conformity with relevant ISO/EN/ASTM/AAMI/ANSI/IEC and other device-related standards that apply to the manufacture, packaging, labelling, reprocessing, traceability including the validation of these processes.
Also we are monitoring these devices using statistics and market observation.

Summary of Testing
All materials used in the composition of AlphaScope Hyseroscopes and their accessories were subjected to performance and physical tests to evaluate safety, effectiveness, and reliability of the devices.
The market observation of AlphaScope Hysteroscope, rigid, with diameter of 2,7 mm has shown that the used materials are not effect the safety of the patients.

All results were in conformance with the cited harmonized device standards and filed.

Information Bearing on the Safety and Effectiveness (807.92)
AlphaScope Hysteroscop has the same intended use as the predicate devices.
It is made of the same materials as one of the predicate device (Alpha Hysteroscope, K012869) and is produced to the same international and FDA-recognized standards.
Slight modifications in design, diameter and material do not adversely affect the safety and effectiveness of these devices.

In summary, the

- Intended use
- Performance attributes
- Materials and
- Basic design

are identical and substantially equivalent to SE devices and to K012869 application.

Labeling

Package Label: All devices are packed in special designed boxes. The Packing was validated (Drop Test).

Affixed to each Box is a label that identifies the enclosed product.
Please see Labels in Appendix V

Every product is carrying the product item number, CE-Mark and Serial Number of the device (Please see description, Appendix VII)

Operating Instructions are delivered with the AlphaScopeHysteroscope.
Please see sample in Appendix I .

Reprocessing and Sterilization

AlpahaScope Hysteroscopes are delivered non-sterile and they were tested for effective Cleaning Possibility and for effective Sterilisation (see Validation report of Nelson Lap, Appendix IV).

All validated Reprocessing and Sterilization instructions are given in the Operating Manual.

Material

Most of the components are Surgical grade stainless steel and in conformance with FDA consensus standards. SE devices are using the same materials for their scopes.

Biocompatibility was tested by MDT (Rigid AlphaHysteroscope)

Standards

DIN 58105 Medical Endoscopes
ISO 8600-1 Endoscopes and Phototonic; General Requirements
ISO 8600-2 Endoscopes and Phototonic; Special Requirements for Bronchoscopes
ISO 8600-3 Endoscopes and Phototonic; Definition of Viewing Field and Viewing Angle
ISO 8600-4 Endoscopes and Phototonic; Definition of maximal size of Insertion part
ISO 8600-5 Endoscopes and Phototonic; Definition of the resolution
ISO 8600-6 Endoscopes and Phototonic; Definitions
DIN EN ISO 9001; Quality Management System
DIN EN 13485 Quality Management System for Medical devices
DIN EN 14971 Requirements for Risk Management Medical devices
DIN EN 60601-2-18; Special Requirements for the Safety including of the basic performance of Endoscopic Equipment
DIN EN ISO 10088-1; Stainless Steel
DIN EN ISO 7153-1; Surgical Instruments; Part 1 Stainless Steel

DIN EN 17664; Sterilization of Medical Devices
DIN EN 1041; Requirements for the Information provided by the Manufacturer
DIN EN 980; Symbols for Identification of Medical Devices
DIN EN 22 248 (ISO 2248) Drop Test
USFDA (21 CFR Part 58) Sterilization Validation
AAMI TIR12:2004
AAMI TIR.2003
ANSI/AAMI ST81:2004
ANSI/AAMI ST89:2006
ASTM E 1837 (1996)
FDA; CRD 183
FDA; CRD 255
FDA; CRD 256
HTM; CRD 259

Non-Clinical Test Results

Based on the equivalence in design and materials to predicate devices, performance testing was not warranted. The device meets the same criteria and is as effective and safe as SE devices.

Tuttlingen, June 22, 2009

Thilo Henzler	Bernd Maier	Klaus Moser	Ulrich Henzler
President	Director	Head of Service	QAM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

GIMMI GmbH
c/o Mr. Ken Blake
V.P. and General Manager
Scanlan International
One Scanlan Plaza
SAINT PAUL MN 55107

FEB 12 2010

Re: K092421
Trade Name: AlphaScope Hysteroscope
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: January 20, 2010
Received: January 25, 2010

Dear Mr. Blake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Abbreviated 510(k)

510(k) Number:

Common Name: Hysteroscope, fiberoptic,

Device Name: AlphaScope Hysteroscope, fiberoptic, operative and diagnostic

Predicate Device Name: The AlphaScope Hysteroscope is substantially equivalent to the following predicate devices:

MicroSpan Gold Hysteroscope (K972426)
Alpha Hysteroscope, Rod Lenses (K012869)

Classification: 21 CFR § 884.1690 Product code 85 HIH
Class II

Indications for Use
AlphaScope Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

AlphaScope Hysteroscope is used with Hysteroscope Sheaths to provide access to the uterine cavity during diagnostic and operative hysteroscopic procedures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092421

Prescription Use ✓ or Over-The-Counter Use